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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,965	06/20/2006	Ezio Bombardelli	2503-1189	7314

466 7590 12/13/2007  
YOUNG & THOMPSON  
745 SOUTH 23RD STREET  
2ND FLOOR  
ARLINGTON, VA 22202

EXAMINER
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MI, QIUWEN

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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12/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/563,965	BOMBARDELLI, EZIO	
	<b>Examiner</b>	<b>Art Unit</b>	
	Qiuwen Mi	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment in the reply filed on 10/22/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

### **Claims Pending**

Claim 13 is newly submitted, which are drawn to the elected Group I. Claims 5, 11, and 12 are cancelled. Claims 1-4, 6-10, and 13 are pending. Claims 3, 6-8, and 10 are withdrawn as they are directed toward a non-elected invention groups or species. Claims 1, 2, 4, 9, and 13 are examined on the merits.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Di Pierro (WO 02/098436 A1), and Znaiden et al (US 5,523,090).

This is a new rejection.

Di Pierro discloses a pharmaceutical and/or cosmetic composition for the treatment of cellulite comprising 0.1-2.5% complex of escin/beta-siterol with phospholipids (the third vasoactive agent), 0.1-2.5% complex of *Ginkgo biloba* dimeric flavonoids with phospholipids (the second vasoactive agent) etc (page 2, lines 20-28). Di Pierro also teaches that the complex of

escin/beta-sitosterol with phospholipids has the same action as escin, but shows a more prolonged release of the active principles and improved bioavailability (page 3, lines 10-13); and the complex of *Ginkgo biloba* dimeric flavonoids with phospholipids, has the same activity as the dimeric *Ginkgo biloba* flavones in the free form, but shows a more prolonged release of the active principles and better bioavailability. *Ginkgo biloba* dimeric flavonoids are extremely potent vasoactive agents due to their inhibitory action on the release of histamine and of the enzyme cAMP phosphodiesterase from mast cells (page 3, lines 13-20). Di Pierro further teaches that the composition of the invention will be formulated in the form of cream, oil, gel, foam, emulsion, milk (page 4, lines 15-20).

Di Pierro does not teach the incorporation of the first vasoactive agent visnadin into the composition.

Znaiden et al disclose an anti-cellulite composition comprising Ginkgo biloba extract (the second vasoactive agent), escin (the third vasoactive agent) etc (col 12, Example 10). Znaiden et al teach that various types of active ingredients may be present in the present invention (col 6, lines 53-56). Suitable vasoactive compounds include but not limited to visnadin etc (col 7, lines 10-15). Znaiden et al also suggest that the topical skin treatment composition of the invention can be formulated as a lotion, a fluid cream, and a gel (col 8, lines 58-67, bridging col 9, lines 1-5).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that it is deemed that the prior art product must not be precluded for use as a vasoactive agent. It is deemed that the composition disclosed by Di Pierro and Znaiden et al. is not precluded for carrying out the intended function of the claims.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

In the instant case, all of the above-listed ingredients were known for treating cellulites. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in treating cellulites.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating cellulites. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in the claims, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and

optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Bombardelli et al and Cho et al since both of them teach topical compositions for treating cellulites individually in the art. Since both of the compositions yielded beneficial results in treating cellulite, one of ordinary skill in the art would have been motivated to make the modifications.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments with respect to references Bombardelli and Cho et al have been considered but are moot in view of the new ground(s) of rejection in light of Di Pierro and Znaiden et al.

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### Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

  
TERRY MCKELVEY, PH.D.  
SUPERVISORY PATENT EXAMINER